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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/686,380 | 10/15/2003 | Theresa Ditter | 47563.0004 | 6318 |
| 57600 7590 07/30/2009 HOLLAND & HART LLP 60 E. South Temple, Suite 2000 P.O. Box 11583 Salt Lake City, UT 84110 | | | | |
| EXAMINER | | | | |
| BLATT, ERIC D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3734 | | | | |
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| 07/30/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,380

Applicant(s)

DITTER, THERESA

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2009 has been entered.

Election/Restrictions

Claims 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made in the reply filed on March 10, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5,545,178) in view of Samuels et al. (US 3,976,079).

Kensey discloses a tissue puncture closure device (Figures 1-5) comprising a carrier tube 88, a filament 42, an anchor 38, a sealing plug 36 comprising a collagen sponge, and a locking apparatus comprising holding member 40 and knot 62 wherein said locking apparatus is separate from the filament, anchor, and sealing plug and is arranged adjacent the sealing plug for compressing the sealing plug along the filament toward the anchor. Samuels discloses an alternate locking apparatus (Figure 14) wherein the locking apparatus comprises a ratchet mechanism. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kensey by providing the locking apparatus of Samuels since this was a known alternative locking apparatus and its substitution would not have produced unexpected results. The modified locking apparatus thus comprises a mechanism that is capable of applying a pressure to the sealing plug to form a seal between the tissue wall puncture and the sealing plug wherein the pressure is insufficient to push the sealing plug through a portion of the internal tissue wall.

Claims 2-11 and 15-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5,545,178) in view of Samuels et al. (US 3,976,079) as applied to claims 1 and 12-14 above, and further in view of Buckman et al. (US 2003/0176890).

Kensey and Samuels disclose the apparatus as recited in claims 2-11 and 15-30 except for the claimed structure of the strap and hub ratchet mechanism. Applicant claims that the strap comprises an elongated track, a plurality of sloping teeth, and a

shoulder stop for limiting movement of the hub, and that the hub comprises a nut having a flexible internal finger wherein said finger comprises a notch or an external corner shaped to mate a surface of the plurality of sloping teeth. Buckman discloses a ratcheting mechanism for holding a sealing member 26 against tissue at a desired pressure comprising the aforementioned elements. (Regarding the claimed shoulder stop, the end of the ratchet track comprises a shoulder stop that limits movement of the hub 28 since the hub will not lock at positions past the stop and will thus be effectively stopped at that position when the sealing member 26 encounters pressure from tissue.) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus taught by Kensey and Samuels by providing the ratchet track and hub of Buckman since this locking mechanism is functionally equivalent to the locking mechanism taught in Samuels and its use would not have produced unexpected results. So modified, the locking apparatus would comprise the claimed elements and would be separate from the filament, anchor, and sealing plug.

Regarding claim 29, Kensey discloses that the insertion sheath 28 comprises a valve 90 at a first end, but fails to disclose a hemostatic valve at a second end. Insertion sheaths comprising valves at the ends thereof were notoriously old and well known in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a hemostatic valve at a second end of the sheath in order to prevent blood or other unwanted fluids from entering the lumen of the insertion sheath.

Response to Arguments

Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/
Examiner, Art Unit 3734

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734